UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC., et al., Plaintiffs, v. INTUITIVE SURGICAL, INC., Defendant.	Case No. 21-cv-03496-VC **ORDER GRANTING IN PART AND DENYING IN PART MOTION TO DISMISS** Re: Dkt. No. 37

Intuitive Surgical makes surgical robots, along with the instruments these robots use during surgery. The company has taken a number of steps to prevent other companies from repairing and refurbishing its instruments, effectively requiring customers to buy new instruments whenever the old ones stop working. One of those companies has sued, contending that Intuitive Surgical's conduct violates the antitrust laws because it forecloses competition in the market for repair and refurbishment of the instruments. The lawsuit also alleges that Intuitive Surgical has violated the Lanham Act by making false claims about these companies in an effort to prevent hospitals from doing business with them in this market.

Perhaps there are procompetitive justifications for the alleged conduct that could carry the day at summary judgment or trial. But no such justifications are before the Court at this early stage in the litigation. Nor has Intuitive Surgical argued that the factual allegations in the complaint are implausible. The arguments that Intuitive Surgical does make in support of dismissal are mostly unconvincing. Accordingly, with a minor exception discussed in Section III.B, the case will go forward.

I

Intuitive Surgical manufactures and sells surgical robots.[1] Since it received FDA clearance in 1999, Intuitive Surgical's "da Vinci" robot has achieved near complete market dominance, with a 99% market share in the worldwide and domestic markets for surgical robots used in minimally invasive soft-tissue surgery. One of the reasons for this market dominance is the benefit of performing surgery using a da Vinci robot, rather than by hand. Without a robot, doctors need to hold surgical instruments while operating, or attach them to some sort of physical support. But the da Vinci robot has arms that hold and move surgical instruments under the control of a surgeon who sits at a console. As a result, "[t]he surgeon is not limited by his or her own physical dexterity in manipulating surgical instruments, but can instead make large scale movements at the console that are translated to precision microscopic movements of surgical instruments."

To perform surgery with a da Vinci robot, a hospital needs two things: the robot and the requisite instrument. Da Vinci robots work only with "EndoWrist instruments," which are manufactured and supplied only by Intuitive Surgical. EndoWrist instruments are not as high tech as the robot itself; they are familiar surgical tools attached to an arm that can be controlled by a da Vinci robot. Indeed, Intuitive Surgical has represented to the FDA that EndoWrist instruments are "essentially identical" to their analogue counterparts—scalpels, clamps, forceps, scissors, etc.

Da Vinci robots typically cost over $2 million. But the real money-maker for Intuitive Surgical is its line of instruments. Each EndoWrist instrument is equipped with a use counter. After a certain number of uses—usually ten—the instrument stops working and must be replaced. As a result, customers are effectively charged based on how much they use their robot. The more surgeries a hospital performs, the more instruments it needs to purchase.

[1] Unless otherwise noted, the facts described in this section come from the well-pleaded allegations in the complaint. As is required at this early stage, all inferences are drawn in favor of the plaintiff. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555–56 (2007).

Enter Surgical Instrument Service Company (SIS). SIS has refurbished and repaired hospital tools for over 50 years. In 2019, SIS decided to expand its services to refurbish EndoWrist instruments, launching a program in which it would inspect the instruments, perform any necessary repairs (such as sharpening or realigning the instrument tip), confirm that the instruments comport with their original specifications, and then—crucially—reset the use counter. By resetting the use counter, SIS made it possible for hospitals to reuse instruments after hitting the use limit, rather than purchasing new ones. This program had the potential to save hospitals a considerable amount of money, as SIS was offering its refurbishment services for 30–45% less than the cost of replacing an EndoWrist instrument. It therefore proved popular: "[j]ust based on its initial contracts, SIS was prepared to service at least 1,500 EndoWrists a month."

But according to the complaint, Intuitive Surgical took a series of actions that effectively foreclosed SIS from entering the market. The contracts between Intuitive Surgical and its customers expressly forbid customers from working with third parties like SIS: when purchasing a da Vinci robot, a customer must agree that it will not have the instruments repaired or refurbished by a third party. And according to the complaint, this is not an empty threat: "[i]f a customer violates this prohibition, Intuitive [Surgical] has threatened to void the warranties on the da Vinci robotic system, completely terminate the agreement with that customer, refuse to provide further service and support for the robotic system, and even render the surgical robot inoperable." In a series of letters and conversations between Intuitive Surgical and its customers in late 2019 and early 2020, Intuitive Surgical reminded its customers of these contractual commitments, while also noting that refurbishment services may be contrary to FDA approval. As a result, "all of SIS's EndoWrist[] customers backed out of their contracts or did not sign contracts under negotiation, effectively eviscerating SIS's EndoWrist repair business."

SIS also alleges that Intuitive Surgical redesigned its instruments to thwart SIS's ability to provide refurbishment services. SIS was able to reset the use counter on the original models of EndoWrist instruments—the S and Si generations. But with the more recent Xi generation, Intuitive Surgical redesigned the internal EndoWrist chip, adding encryption and other measures

that prevented parties like SIS from resetting the counter. SIS alleges that "there is no technical or safety justification" for these design changes, and that Intuitive Surgical's "sole purpose" in making the changes was "to prevent competition in repair services and to unjustifiably protect its supra-competitive EndoWrist profits." SIS further alleges that Intuitive Surgical has taken steps to force customers to move from S and Si generation to Xi generation robots by ceasing to sell S and Si model instruments and by discontinuing technical support for S and Si robots.

SIS claims that Intuitive Surgical's actions violate the antitrust laws. First, SIS asserts that the contractual constraints Intuitive Surgical places on its customers—which together prohibit customers from having their EndoWrist instruments refurbished by third parties—constitute a "restraint of trade" in violation of Section 1 of the Sherman Act. 15 U.S.C. § 1.[2] Second, SIS alleges that Intuitive Surgical violated Section 2 of the Sherman Act through a series of exclusionary tactics, including "tying EndoWrist replacements and repairs to sales and servicing of da Vinci surgical robots," sending cease and desist letters when customers attempted to have their EndoWrist instruments refurbished by third parties, and redesigning its instruments to prevent third-party services from resetting the use counter on its instruments. 15 U.S.C. § 2. Finally, SIS brings an attempted monopolization claim under Section 2 based on this same conduct.

SIS also asserts that Intuitive Surgical violated the Lanham Act by making false and misleading statements to its customers. 15 U.S.C. § 1125. SIS raises two Lanham Act claims based on two sets of Intuitive Surgical's alleged statements: that SIS's services are contrary to FDA approval, and that SIS's services violate Intuitive Surgical's intellectual property rights.

II

Intuitive Surgical makes two arguments for dismissal of the antitrust claims. First, it contends that all of the antitrust claims must be dismissed because SIS has not adequately alleged the relevant market in which the anticompetitive conduct occurred. Second, Intuitive

[2] In its complaint, SIS argues that these constraints are unlawful under two legal theories—"tying" or "exclusive dealing."

Surgical argues that, at a minimum, SIS's monopolization claim must be dismissed to the extent it is based on the company's decision to redesign its EndoWrist instruments, because such allegations amount to a facially deficient refusal-to-deal claim.

A

To state a claim under the antitrust laws, a plaintiff must identify the relevant market that has been affected by the challenged conduct. *See Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 459 (1993); *Jefferson Parish Hospital District No. 2 v. Hyde*, 466 U.S. 2, 21 (1984). SIS claims that Intuitive Surgical has harmed competition in the "EndoWrist instrument aftermarket"—i.e., the "worldwide and domestic markets for repair and replacement of instruments for surgical robots [used] for minimally invasive soft tissue surgery."[3] Intuitive Surgical challenges this market definition, contending that SIS has not plausibly alleged that EndoWrist instruments (and their subsequent repair or replacement) occupy a distinct market from the da Vinci robots with which they are used.

In an antitrust case, "whether one or two products are involved turns not on the functional relation between them, but rather on the character of the demand for the two items." *Jefferson Parish*, 466 U.S. at 19.[4] To plead the existence of two products, the plaintiff must allege facts from which the court can plausibly infer that the products exist in separate markets. *See Kentmaster Manufacturing Co. v. Jarvis Products Corp.*, 146 F.3d 691, 695 (9th Cir. 1998). Allegations of consumer choices can satisfy this requirement—separate markets exist in situations where consumers, "when given a choice," opt to purchase the goods from different firms, rather than a single firm. *See Rick-Mik Enterprises, Inc. v. Equilon Enterprises LLC*, 532 F.3d 963, 975 (9th Cir. 2008) (quoting *United States v. Microsoft Corp.*, 253 F.3d 34, 86 (D.C.

[3] SIS describes its services as the "repair" or "refurbishment" of EndoWrist instruments. This ruling follows its lead and uses these two terms interchangeably.

[4] The issue of whether a good occupies one product market or two typically arises in antitrust cases with tying claims, because, to state a tying claim, a plaintiff must allege that "two separate product markets have been linked." *Jefferson Parish*, 466 U.S. at 21. Here, Intuitive Surgical's argument goes beyond SIS's tying claim, challenging all of the antitrust claims. Still, the relevant precedent is primarily antitrust cases with tying claims.

Cir. 2001)).

The Supreme Court has long recognized that complementary products—however essentially paired—can constitute separate product markets. *See Eastman Kodak Co. v. Image Technical Services, Inc.*, 504 U.S. 451, 462–63 (1992). This remains true even if demand for one product hinges on demand for another. *Id.* at 463. If complementary products could never occupy distinct product markets, "there [could] never be separate markets, for example, for cameras and film, computers and software, or automobiles and tires." *Id.*

Against this backdrop, SIS has met its pleading-stage burden, plausibly alleging the existence of distinct product markets by virtue of the alleged consumer demand. When SIS sought to provide EndoWrist instrument refurbishment services, it found success, "enter[ing] into service contracts with a number of health care providers" that "would have been worth millions in annual revenue to SIS." These allegations, if true, would constitute evidence of consumer demand for instrument refurbishment services distinct from the market for surgical robots. "[W]hen given a choice," health care providers opted to purchase refurbishment services from SIS, not from Intuitive Surgical. *Rick-Mik Enterprises*, 532 F.3d at 975 (quoting *Microsoft*, 253 F.3d at 86).

Intuitive Surgical counters that these cannot be separate markets because EndoWrist instruments are an "essential component" of the da Vinci surgical robotic system. Essential components, Intuitive Surgical argues, can never be separate products. But this argument runs headlong into *Eastman Kodak*. There, the Court recognized that the market for photocopier replacement parts could be distinct from the market for photocopier servicing—even though there was "no demand for parts separate from service"—because the plaintiffs had presented sufficient evidence of consumer demand for service and parts sold separately *Eastman Kodak*, 504 U.S. at 463.

Intuitive Surgical points to *Kentmaster Manufacturing Co. v. Jarvis Products Corporation*, in which the Ninth Circuit held that slaughterhouse equipment and spare parts constituted a single product because "only an idiot would think of the cost of [the equipment]

without taking into account the cost of [spare parts]." 146 F.3d at 694. Intuitive Surgical argues that the same is true on these facts: no hospital would purchase a da Vinci robot without factoring in the cost of the instruments it would need to buy in the future. But *Kentmaster* cannot stand for the proposition that product complements can never make up separate product markets—such a holding would conflict with controlling Supreme Court precedent. Rather, in *Kentmaster*, the Ninth Circuit distinguished *Eastman Kodak* on the basis that the complaint had not alleged any consumer demand for one product apart from the other: "on the face of the complaint, [the] equipment and spares are described so that they necessarily constitute a single product." *Id.* at 695. *Kentmaster* is thus an example of a complaint failing to adequately allege consumer demand for the items as distinct products. The complaint here does not have this deficiency.

Finally, the various franchise cases cited by Intuitive Surgical are not analogous to the facts here. *See Rick-Mik Enterprises, Inc. v. Equilon Enterprises LLC,* 532 F.3d 963 (9th Cir. 2008); *Siva v. American Board of Radiology*, 418 F. Supp. 3d 264, 274 (N.D. Ill. 2019). In the context of franchise agreements, a franchisee enters into a contract with a franchisor that consists of a bundle of rights and restrictions. In the ordinary case, the contractual restrictions on a franchisee do not occupy distinct product markets from the franchise agreement as a whole because this type of contractual bundle "is consistent with the existence of a competitive market in which franchises are valued, in part, according to the terms of the proposed franchise agreement and the availability of alternative franchise opportunities." *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 441 (3d Cir. 1997). This reasoning is "grounded . . . in the fact that the primary market for franchise agreements is a competitive market"—if potential franchisors do not like the terms of Domino's franchise agreement, they can open a Pizza Hut instead. *Newcal Industries, Inc. v. Ikon Office Solution*, 513 F.3d 1038, 1046 (9th Cir. 2008). The constraints on the franchisee's future purchases are therefore not due to the leveraging of market power, but flow from the "contractual rights that consumers knowingly and voluntarily gave to the defendant." *Id.* at 1048. Therefore, franchise agreements are characterized as a single

product—not multiple products tied together.

Here, the primary market is not competitive—Intuitive Surgical has a monopoly in the market for surgical robots used in minimally invasive, soft-tissue surgery. According to the allegations in the complaint, Intuitive Surgical's ability to forbid health care providers from purchasing refurbishment services from other suppliers flows not from a voluntary choice by health care providers in a competitive market, but from Intuitive Surgical's monopoly power. Unlike the franchise cases, then, it makes sense (at least at the pleading stage) to conceptualize the market for refurbishment services separately from the market for surgical robots. Intuitive Surgical's motion to dismiss the complaint for failing to allege a relevant market is therefore denied.

B

As part of its Section 2 monopolization claim, SIS alleges that Intuitive Surgical redesigned its EndoWrist instruments for the sole purpose of preventing the emergence of competitors like SIS. Intuitive Surgical has moved to dismiss "SIS's antitrust claims relating to Xi instruments" because the "allegations regarding Intuitive [Surgical]'s usage counter for Xi instruments constitute a facially deficient 'refusal to deal' theory."

To begin, this appears to be an improper argument for a motion to dismiss; a court dismisses claims, not allegations. The allegations concerning the Xi instruments are one of the exclusionary tactics SIS cites as part of its monopolization claim, not a claim in itself.

But in any event, Intuitive Surgical's argument does not prevail because SIS's allegations fit within the scope of product redesign challenges that are cognizable under the antitrust laws. "[C]hanges in product design are not immune from antitrust scrutiny and in certain cases may constitute an unlawful means of maintaining a monopoly under Section 2." *Allied Orthopedic Appliances Inc. v. Tyco Health Care Group LP*, 592 F.3d 991, 998 (9th Cir. 2010). To count as unlawful exclusionary conduct, a firm must not have had any "procompetitive justification" for its design change. *Id.* (quoting *Microsoft*, 253 F.3d at 59). SIS has alleged exactly that. According to the complaint, "[t]here is no technical or safety justification" for Intuitive

Surgical's redesign of the use counter in its Xi generation EndoWrist instruments; rather, Intuitive Surgical redesigned the use counter for the "sole purpose" of "prevent[ing] competition."[5] SIS alleges that Intuitive Surgical then "t[ook] steps to force customers to switch" from earlier generations of instruments (for which the use counter can be reset) to the new version (for which it cannot be) to prevent the emergence of third-party repair services. SIS has not challenged Intuitive Surgical's decision to design a product with a use counter in the first instance, but the subsequent addition of "encryption and other countermeasures" in the Xi generation that prevent the use counters from being reset by third parties. This is therefore not a refusal-to-deal claim, and SIS need not allege a prior course of dealing between SIS and Intuitive Surgical. On this point, the Court disagrees with *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, 2021 WL 1227593 (M.D. Fl. Mar. 8, 2021).

III

In addition to its antitrust claims, SIS brings two claims under the Lanham Act, asserting that Intuitive Surgical misleadingly told customers that: (1) SIS's services are contrary to FDA approval; and (2) SIS's services violate Intuitive Surgical's intellectual property rights. Intuitive Surgical has moved to dismiss both claims, arguing that the first is precluded by the Food, Drug, and Cosmetic Act (FDCA) and that the second is insufficiently pled. The motion to dismiss is denied with respect to the first claim but granted with respect to the second.[6]

A

The Lanham Act creates a private right of action against commercial actors who make any "false or misleading representation of fact . . . in commercial advertising or promotion" that "misrepresents the nature . . . of his or her or another person's goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1). The statute provides that any person who "is or is likely to be

[5] Presumably Intuitive Surgical will offer procompetitive justifications for this design change at summary judgment, but it has not done so in this motion.

[6] The complaint includes both of these claims under the same label, titled "Count V–Unfair Trade Practices–Violation of Lanham Act." But how a plaintiff labels their claims is not what matters. What matters is whether a set of allegations constitutes one claim or several distinct legal claims. In this instance, the two alleged misrepresentations appear distinct.

damaged by such act" may bring suit. *Id.*

Notwithstanding the text of the Act, Intuitive Surgical argues that SIS's claim is precluded by a separate statute—the FDCA. A Lanham Act suit cannot be brought, Intuitive Surgical contends, when adjudicating the claim would require a court to evaluate the lawfulness of a firm's activity under the FDCA.

That argument is wrong. As the Supreme Court has recognized, the FDCA and the Lanham Act are complementary enforcement schemes. *See POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 118 (2014). Although both impact the representations a company can make about its medical devices, "the Lanham Act protects commercial interests against unfair competition, while the FDCA protects public health and safety." *Id.* at 115. The FDCA does not limit the reach of the Lanham Act; it merely creates another type of enforcement action alongside it.

In Intuitive Surgical's view, this case is controlled by a Ninth Circuit opinion predating the Supreme Court's decision in *POM Wonderful*: *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010). But *PhotoMedex* is no longer good law. In *PhotoMedex*, the Ninth Circuit dismissed the plaintiff's Lanham Act claim, holding that "a private action brought under the Lanham Act may not be pursued when . . . the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation." *Id.* at 924. Four years later, the Supreme Court held in *POM Wonderful* that the FDCA did not preclude a Lanham Act claim in a slightly different context—a challenge to an allegedly misleading drink label. 573 U.S. at 106. Although *POM Wonderful* concerns the relationship between the Lanham Act and the provisions of the FDCA dealing with the misbranding of food and drink, its logic applies with equal force to the statutory relationship at issue in *PhotoMedex*: the relationship between the Lanham Act and the sections of the FDCA involving medical-device approval.

First, "neither the Lanham Act nor the FDCA, in express terms, forbids or limits Lanham Act claims challenging" statements about medical devices "that are regulated by the FDCA." *Id.*

at 113. Second, given the fact that the Lanham Act and the FDCA have coexisted for over seventy years, "[i]f Congress had concluded, in light of experience, that Lanham Act suits could interfere with the FDCA, it might well have enacted a provision addressing the issue." *Id.* Finally, as was the case in *PhotoMedex*, Congress has expressly pre-empted state regulations in this area. *See* 21 U.S.C. § 360k. "By taking care to mandate express pre-emption of some state laws, Congress if anything indicated it did not intend the FDCA to preclude requirements arising from other sources." *POM Wonderful*, 573 U.S. at 114. The "reasoning [and] theory" of *PhotoMedex* is therefore "clearly irreconcilable with the reasoning [and] theory" of *POM Wonderful*, making *PhotoMedex* "effectively overruled." *See Lair v. Bullock*, 697 F.3d 1200, 1206 (9th Cir. 2012) (quoting *Miller v. Gammie*, 335 F.3d 889, 893 (9th Cir. 2003)).[7]

Even if *PhotoMedex* were not overruled, SIS's Lanham Act claim would not be precluded. *PhotoMedex* concerned a medical device manufacturer that represented that its product was "FDA Approved." 601 F.3d at 923. A competitor brought a lawsuit under the Lanham Act, arguing that the manufacturer "violated the FDCA by misrepresenting that its product had received FDA clearance," even though "the FDA declined to make a finding that there was no valid clearance or to bring an enforcement action itself." *Id.* at 922. This lawsuit presents the inverse scenario. SIS is not seeking to prove that Intuitive Surgical violated the FDCA; rather, it is arguing that Intuitive Surgical's representation that SIS may have violated the FDCA was misleading. The concern in *PhotoMedex* was overlapping authority: the Ninth Circuit found that the plaintiff's Lanham Act claim was precluded because only the FDA had the authority to take action against the defendant for its potential misrepresentation. *See id.* at 925. But here—as Intuitive Surgical acknowledged in the hearing on the motion to dismiss—there is no issue of duplicate enforcement: the FDA does not police statements that market participants make about their competitors, even when those statements concern medical devices. Therefore, even under the now-defunct reasoning of *PhotoMedex*, the Lanham Act claim based on Intuitive

[7] "[T]his standard applies not only to three-judge panels but also to district courts within [the Ninth] [C]ircuit." *Id.*

Surgical's statements regarding FDA approval is not precluded by the FDCA.[8]

B

Finally, Intuitive Surgical argues that SIS has not stated a Lanham Act claim with respect to Intuitive Surgical's alleged statements about its intellectual property rights. On this point, Intuitive Surgical is correct. SIS claims that "Intuitive . . . made misleading statements that use of refurbished EndoWrists would violate [Intuitive Surgical's] intellectual property rights." But the only allegation in support of this claim is that Intuitive Surgical made a "misleading statement . . . by letter" that referred to "unspecified 'intellectual property rights in the da Vinci systems and its instruments' that 'Intuitive believes it has[.]'" This is not enough—setting aside SIS's legal characterization of Intuitive Surgical's statements, the mere fact that Intuitive Surgical referenced its intellectual property in an unspecified letter to its customers is insufficient to plausibly allege that it made a "false or misleading representation of fact" in violation of the Lanham Act. 15 U.S.C. § 1125(a)(1); *see Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). This claim is therefore dismissed with leave to amend.[9]

* * *

The motion to dismiss is largely denied. Dismissal of the Lanham Act claim relating to representations about Intuitive Surgical's intellectual property rights is with leave to amend. In the unlikely event that SIS opts to file an amended complaint, it is due within 21 days of this order. Discovery may move forward immediately.[10]

[8] Of course, Intuitive Surgical may be correct that evaluating the merits of this Lanham Act claim will require this Court to "decide whether, under the FDCA and its regulations," SIS's services are proper. *PhotoMedex*, 601 F.3d at 928. But this is no concern. Courts regularly evaluate the lawfulness of a party's behavior under federal regulations. That the regulations here come from the FDA make no difference.

[9] Intuitive Surgical's request for judicial notice of its Patent Notice webpage is denied as moot because this claim is insufficient even without considering this webpage. *See* Dkt. No. 38.

[10] SIS's motion for leave to commence discovery, noticed for hearing on January 6, 2022, is denied as moot. *See* Dkt. No. 69.

IT IS SO ORDERED.

Dated: November 23, 2021

VINCE CHHABRIA
United States District Judge